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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

DOWE, KATHERINE MARIE

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

05/11/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/801,231	Applicant(s) BUCAY-COUTO ET AL.	
	Examiner KATHERINE M. DOWE	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 and 31 is/are pending in the application.
- 4a) Of the above claim(s) 24-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The following is in response to the amendment filed February 3, 2010.
2. Claims 1-29 and 31 are currently pending, with claims 24-29 withdrawn from consideration.

Claim Rejections - 35 USC § 112

3. The amendment to claim 21 is acknowledged. Accordingly, the rejection of the claim under 35 U.S.C. 112, second paragraph, as set forth in the last Office Action is hereby withdrawn.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites the crosslinked polymeric body further comprises a therapeutic agent. However, parent claim 1 recites the first fluid comprises a therapeutic agent, wherein the first fluid forms a portion of the crosslinked polymeric body when it is incorporated within the second crosslinkable polymer. It is unclear if the "therapeutic agent" of claim 20 is the same as that recited in claim 1, or if claim 20 is referring to a second therapeutic agent. For the purpose of examination, the therapeutic agent of claim 20 is being interpreted as the same therapeutic agent recited in claim 1.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1-9, 11-23, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawhney (US 6,818,018) in view of Weikel et al. (US 6,632,235, hereinafter "Weikel"). Regarding claims 1-8, 20, 21, and 31, Sawhney discloses the invention substantially as claimed including injecting a crosslinkable polymer (second fluid) and crosslinking agent to a target location within the body, such that the crosslinkable polymer is crosslinked in situ to form a solid or semisolid crosslinked polymer at the target location (col 6, ll 5-16; col 8, ll 25-29; col 18, ln 50 – col 19, ln 9; col 21, ll 44-58). Furthermore, a first fluid comprising a non-crosslinkable polymer (release rate modification agent – col 18, ll 23-38) and a therapeutic agent (col 16, ln 10 – col 17, ln 65) is injected along with the crosslinkable polymer and crosslinking agent, such that the crosslinkable polymer coats the first fluid to form a solid crosslinked polymer containing the first fluid upon reaction of the crosslinkable polymer with the crosslinking agent (col 15, ln 66 – col 16, ln 2). Sawhney disclose several polymer choices for both the non-crosslinkable polymer of the first fluid and the crosslinkable polymer of the second fluid (see above citations). It would have been prima facie obvious to try modifying the method of Sawhney to choose the materials such that the chosen crosslinkable polymer for the second material was less viscous than the chosen non-crosslinkable polymer for the first material to allow the second material to sufficiently coat the second material in an attempt to provide an improved drug loaded hydrogel as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp and since it is obvious to choose from a finite number of identified, predictable solutions with a reasonable expectation of success.

However, Sawhney discloses the fluids are directly injected into the target location and do not teach injecting the fluids and crosslinking agent into a container positioned within the target location. Wiekel discloses a similar method for forming a crosslinking a polymer in situ and teach the crosslinking agent and crosslinkable polymer are injected into a container (30)

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positioned within the subject (col 6, ll 5-13; col 10, ll 58-61; col 11, ll 27-37). By injecting the elements into a container placed within the subject, more controlled deployment of the crosslinked polymer may be obtained and the risk of polymeric precursors to other areas of the body is reduced (col 6, ll 5-13). The container is an expandable balloon, which may have elastic or inelastic walls (col 1, ll 58-60). Upon solidification of the polymer, the container may be removed to release the solidified polymer within the target area (col 6, ll 5-13; col 7, ll 16-25) or the container may be biodegradable and be released within the patient along with the solidified polymer (col 7, ll 26-43). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Sawhney such that first fluid, second fluid, and crosslinking agent were injected into a container placed within the target location as taught by Wiekel to ensure the first fluid, second fluid, and crosslinking agent do not migrate from the target location prior to solidification/crosslinking of the second fluid.

Regarding claim 9, the crosslinked polymeric body may be biodisintegrable (col 4, ll 52-55).

Regarding claims 11-19, the crosslinked polymeric body may be formed within a body cavity, a bodily lumen, at a surgically created site, within an aneurysm, or within a uterine fibroid tumor, wherein the crosslinked polymeric body may be an antiadhesive body, an embolic body, a bulking agent, or tissue scaffold (col 4, ll 56-61).

Regarding claims 22 and 23, an additional fluid comprising an additional crosslinkable polymer may be injected and crosslinked in situ to form a solid polymeric body comprising a plurality of polymers (col 10, ll 11-30).

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sawhney (US 6,818,018) and Weikel (US 6,632,235), as applied to claim 1 above, further in view of Spacek

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(US 6,524,327). Sawhney and Weikel disclose the invention substantially as claimed as shown above. However, they do not disclose the method comprises washing the crosslinked polymeric body prior to releasing the crosslinked solid polymeric body. Spacek discloses a method for forming a solid polymeric body in situ and teaches once the crosslinking, or bonding, is complete, the polymeric body should be washed to remove unreacted reactants and any byproducts to ensure biocompatibility. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Sawhney and Weikel such that the step of washing the solid polymeric body was added to remove byproducts and reactants that may harm the body.

Response to Arguments

9. Applicant's arguments with respect to claims 1-23 and 31 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE M. DOWE whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Dowe
May 7, 2010

/K. M. D./
Examiner, Art Unit 3734

/TODD E. MANAHAN/

Supervisory Patent Examiner, Art Unit 3734